

National Cancer Institute  
Institutional Review Board  
**AGENDA (revised 2/2/15)**  
**February 9, 2015**  
1:00 – 5:00 pm  
10 CRC/3-1608

- 1. Review of Draft Minutes, January 26, 2015**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Initial Review** P142108, "Phase I Trial of 4'-thio-2'-deoxycytidine (TdCyd) in Patients With Advanced Solid Tumors" - Jim Doroshow, PI
- 9. Amendment** 02C0140Q, "A Prospective National Study to Molecularly and Genetically Characterize Human Gliomas: The Glioma Molecular Diagnostic Initiative" - Ronald Gress, PI
- 10. Amendment** 13C0063G, "A Phase I, Open-label, Multiple-Ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C, a Monoclonal anti-PD-L1 antibody, in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications" - James Gulley, PI
- 11. Amendment** 03C0278M, "A Comparative Study of Pediatric CNS Tumor Activity as Assessed by 18F-FDG PET Imaging and Proton Magnetic Resonance Spectroscopic Imaging (1H-MRSI)" - Kathy Warren, PI
- 12. Initial Review** P141528, "Phase I/II Study of Nivolumab (IND#124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab"—Crystal Mackall, PI